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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,077	02/12/2002	Thomas R. Gadeck	9491-058-27	3125

7590 09/21/2004

Supervisor, Patent Prosecution Services  
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EXAMINER
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COUNTS, GARY W

ART UNIT	PAPER NUMBER
	1641

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/073,077	GADEK ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Gary W. Counts	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on August 18, 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/26/02</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of Group I Claims 1-14 in the reply filed on August 18, 2004 is acknowledged. The traversal is on the ground(s) that examination of all claims as originally filed without restriction would not work an undue burden on the Examiner in that a search of the prior art for all of the claims would be identical or substantially similar. This is not found persuasive because of reasons of record and further, while the searches would be expected to overlap; there is no reason to expect the searches to be coextensive. Also, the different Groups require different search terms and a different search strategy which creates a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble recites a method for identifying compounds that bind to a target of interest. However, there is no positive recitation in the body of the claim identifying a compound.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step to identify the ligands that bind to the first and second binding sites because one would want to know what has bound before combining to form the linked ligands. As indicated by Applicant on page 20, lines 27-29, individual members of sets of target binding ligands are identified during the assembling steps.

Claim 1 is vague and indefinite because it is unclear how Applicant is linking the two bound members. For example, if the two members are bound to the target does Applicant somehow cause the members to dissociate and recover the members and then chemically link the members or does Applicant somehow identify the two members bound to the target and then synthesize a molecule using members that correspond to the members that were bound to the target or does applicant link the two members while they are bound to the target. Please clarify.

Claim 1, line 9 the recitation "identify members" is vague and indefinite. It is unclear if applicant is referring to the compounds in line 1 or if applicant is referring to something else. Please clarify.

Claim 1, step (d) is vague and indefinite because it is unclear how the linked ligand is screened. Is the linked ligand compared to other ligands or is the linked ligand detected by itself to see if binding has occurred or does Applicant intend something else.

Claim 5 is vague and indefinite. It is unclear what applicant intends. Is Applicant saying that binding site one and two are located at the same position or does Applicant intend that there are two different binding sites which are structurally the same. Please clarify.

Claim 11, line 2 the recitation "biological measurement" is vague and indefinite. It is unclear what applicant intends. There is no definition provided for the term in the specification.

#### ***Allowable Subject Matter***

5. Claims 1-14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record neither teaches nor suggest a method for identifying a compounds that bind a target of interest comprising assembling a first set of target binding ligands that compete for non-covalent binding to a first binding site on the target; assembling a second set of target binding ligands that compete for non-covalent

binding to a second binding site on the target; chemically linking at least one member of the first set and at least one member of the second set to provide a first set of linked ligands; and screening the set of linked ligands to identify members thereof that bind to the target.

The closest reference is Ellman et al (US 6,344,330). Ellman et al disclose pre-screening a population of small organic compounds to identify those that are capable of binding to the molecular target. Ellman et al disclose that the small organic compounds that are identified during the pre-screening as capable of binding to the target are then chemically coupled in various combinations with a linker element to provide a library of potential ligands for binding to the target molecule that is then screened to identify ligands having very high binding affinities for the molecular target. However, Ellman et al does not teach nor suggest a method for identifying a compounds that bind a target of interest comprising assembling a first set of target binding ligands that compete for non-covalent binding to a first binding site on the target; assembling a second set of target binding ligands that compete for non-covalent binding to a second binding site on the target; chemically linking at least one member of the first set and at least one member of the second set to provide a first set of linked ligands; and screening the set of linked ligands to identify members thereof that bind to the target.

### ***Conclusion***

6. No claims are allowed.

Art Unit: 1641

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Erlanson et al (US 2002/0150947) disclose a tethering method for the rapid identification of at least two binding partners that bind near one another to a target molecule.

Crooke et al (US 2002/0102572) disclose methods for determining the relative affinity of a ligand for the biomolecular target it interacts with and also discloses methods for screening ligand or combinatorial libraries of compounds against one or more than one biological target molecules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
September 8, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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09/17/04